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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,725	09/16/2003	Siau-Way Liew	3155/119	4659
75059 7590 12/28/2010 Sunstein Kann Murphy & Timbers LLP 125 SUMMER STREET BOSTON, MA 02110-1618				
EXAMINER RAMIREZ, JOHN FERNANDO				
ART UNIT		PAPER NUMBER		
3777				
NOTIFICATION DATE		DELIVERY MODE		
12/28/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@SUNSTEINLAW.COM

Office Action Summary

Application No.

10/665,725

Applicant(s)

LIEW ET AL.

Examiner

JOHN F. RAMIREZ

Art Unit

3777

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03/01/10.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-10,12-55,89-99,101-184 is/are pending in the application.
4a) Of the above claim(s) 1-6,9-10,14-55,106-115,131-172 and 174-184 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 12,13,89-99,101-105,116-130 and 173 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date 10/29/10,05/10/10
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

Applicant's arguments filed on 10/29/10 have been fully considered but they are not persuasive.

Newly submitted claims 185-210 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 185-210 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant alleges that the Grunkin et al. reference do not teach or suggest the steps of performing a pixel neighborhood analysis on the structure identified within the trabecular pattern to identify parameters such as: total area, perimeter, segments, nodes, etc. to gather information on the complexity of the trabecular structure. However, the examiner of record respectfully disagrees with applicant's comments. In column 15, lines 58-67 and column 16, lines 1-15, the specifications of the Grunkin et al. patent specifically states:

Extraction of Statistical Features

Naturally, it is preferred to extract features that, in some sense, quantify the properties (such as structure and density) of the trabecular structure. Not surprisingly, the meshes of the PTP-net are much larger, and often broken, for osteopenic individuals than for non-osteoporotic individuals. This difference may be quantified in several ways. Such properties are, e.g., reflected in the average distance from each background pixel to the nearest foreground pixel (bone-pixel) in the projected trabecular pattern.

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The size of the dark meshes in the pattern is a relevant parameter that is conveniently quantified by calculating the so-called distance transform for the projected trabecular pattern. The result of the distance transform on the PTP is shown in FIG. 9 and is denoted $X_D(r,c)$.

In addition, for each background pixel in the projected trabecular pattern, a line is drawn from the pixel, in a given direction, until a foreground pixel ("bone-pixel") is found. The distance between these pixels is measured. This is done for a fixed number of directions as illustrated in FIG. 10. After this, the average distance which is referred to as the star area, denoted $X_A(r,c)$, or the maximum star length which is denoted $X_X(r,c)$ may be calculated. These images are shown in FIG. 11 and FIG. 12 respectively.

Based on the above evidence, the method disclosed by Grunkin et al. teach or suggest performing a pixel neighborhood analysis on the structure identified within the trabecular pattern to identify parameters such as: total area, perimeter, segments, nodes, etc. to gather information on the complexity of the trabecular structure. Therefore, the rejection is maintained and repeated below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 89-91, 93-99, 101-103, 118-119, 128-129 and 173 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (US 6,442,287) in view of Grunkin et al. (US 5,915,036) of record.

Jiang discloses an automated method for analyzing bone wherein the strength of the bone is estimated. Multiple variables, including population data such as age of the patient, were used to determine the strength of bone and thus the likelihood of risk of future fracture. One of the variables is the 3D orientation of the trabecular network. Since 3D trabecular orientation is invasive or destructive, Jiang uses texture orientation to estimate the 3D structural information of the 3D orientation of the trabecular network from a non-invasive and non destructive projection radiograph (two-dimensional image).

This extracted structural features is then further used to generate texture information such as the Minkowski dimension (fractal dimension) and the volumetric bone mass density (abstract, col. 6 line 27-65, col. 17 line 15-47, col. 20 line 22-42, see figs. 1A and 22). However, Jiang does not explicitly disclose performing a pixel neighborhood analysis on the structure identified within the trabecular pattern to identify at least two parameters from the group consisting of total area, trabecular perimeter,

node count (N), segment count (S), node-to-free-end segment count (NF), and mean distance transform values for each connected skeleton.

In the same field of endeavor, Grunkin et al. teach a method for analyzing bone wherein the strength of the bone is estimated and thus the likelihood of risk of future fracture (see abstract, col. 1, lines 3-7, col. 4, lines 35-63). Multiple variables, including micro-structural parameters (col. 4, lines 5-14), macro-anatomical parameters and biomechanical parameters (see claim 33, col. 10, lines 25-29) of a vertebrate were analyzed and evaluated based on x-ray imaging information (col. 1, lines 44-49, col. 14, lines 21-41) relating to the trabecular structure to determine the strength of bone (col. 2, lines 1-36). Further, Grunkin et al. disclose the steps of performing a pixel neighborhood analysis on the structure identified within the trabecular pattern to identify parameters such as: total area, perimeter, segments, nodes, etc. to gather information on the complexity of the trabecular structure (col. 15, lines 58-67 and col. 16, lines 1-15).

Based on the above observations, for a person of ordinary skill in the art, modifying the method disclosed by Jiang et al., with the above discussed enhancements would have been considered obvious because such modifications would have provided a more reliable estimation of the bone quality (col. 3, lines 22-24).

Claims 116-117, 120-126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumagai (US 6,306,822 B 1) in view of Jiang et al. (US 6,442,287) in view of Grunkin et al. as claimed above in claim 12.

Kumagai discloses a method for treating or preventing any condition associated with bone loss through administering an agent to the subject. The bone quality measurement is first measured on day 0, before treatment begins, then again on day 45 and day 90. The bone quality is then compared, showing the effectiveness of each of the agents on remodeling the bone (fig. 5, col. 13 lines 60-63). Kumagai does not disclose the specifics on how they measure the bone density. It would be obvious to one skilled in the art at the time of the invention to use any method that is well known in the art such as the method that is disclosed in Jiang et al. in view of Grunkin et al. as explained above.

Claims 92 and 104-105 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jiang et al. (US 6,442,287) in further view of Grunkin et al. as claimed above in claim 12.

In regards to **claims 104-105**, Jiang et al. disclose an automated method for analyzing bone wherein the strength of the bone is estimated and analyzed (see abstract). Jiang et al. do not disclose the total bone factor as claimed in claim 13, and converting the 2D pattern into a 4D pattern as claimed in claims 104, 105 and 113.

It would have been an obvious design choice for one of ordinary skill in the art at the time for the invention to have expected Jiang et al. method and applicant's invention, to perform equally well. Furthermore, it would have been prima facie obvious to one of ordinary skill in the art to have modified the method disclosed by Jiang et al. in view of Grunkin et al. as discussed above in claim 12, to obtain the invention as

specified in claims 104-105 and 113 because such a modification would have considered a mere design consideration which fails to patentably distinguish over the prior art of Jiang et al in view of Grunkin et al.

In regards to **claim 92**, it would have been prima facie obvious to one of ordinary skill in the art to have modified the method disclosed by Jiang et al. in view of Grunkin et al. as discussed above in claim 12, by using the image of a horse to analyze bone mass and structure for the assessment of bone strength and/or osteoporosis since it is well known that osteoporosis can occur in both human and animal subjects.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN F. RAMIREZ whose telephone number is (571)272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chen Robert can be reached on (571) 272-3672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. R./
Examiner, Art Unit 3777

/Tse Chen/
Supervisory Patent Examiner, Art Unit 3777